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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
RINES, ROBERT D	

ART UNIT	PAPER NUMBER
3626	

MAIL DATE	DELIVERY MODE
10/18/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/086,253	RINCAVAGE ET AL.	
	Examiner	Art Unit	
	Robert D. Rines	3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 July 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6 and 8-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6 and 8-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Notice to Applicant

[1] This communication is in response to the amendment filed 16 July 2007. Claims 1-3, 5, 8-9, 11-12, and 17-18 have been amended. Claims 1-6 and 8-20 are pending.

Rejections of claims 1-6 and 7-20 are maintained as set forth in the previous Office Action mailed 8 March 2007, herein incorporated by reference. Applicant's amendments to claims 1-3, 5, 8-9, 11-12, and 17-18 are addressed below. Applicant's remarks filed 16 July 2007 are addressed in the context of rejections of independent claims 1 and 12 set forth below.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

[2] Claims 1-6, 8-9, and 12-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Denny (United States Patent Application Publication #2004/0107117) in view of Borsand et al. (United States Patent Application Publication #2003/0074225).

As per (currently amended) claim 1, Denny teaches a method of analyzing changes made to a medical prescription by a pharmacist that fills said medical prescription, said method comprising the steps of: providing a database (Denny; paragraph [0064]); entering unfilled prescription data into said database (Denny; paragraph [0060]), wherein said unfilled prescription data corresponds to a prescription that had been prescribed by a physician to a particular patient (Denny; paragraphs [0010] [0027] [0030] [0031]), and wherein said unfilled prescription data contains information regarding a recommended pharmaceutical type and a recommended quantity prescribed in said prescription (Denny; paragraph [0031]); retrieving said unfilled

prescription data from said database by a pharmacist selected by said particular patient to fill said prescription (Denny; paragraphs [0011] [0012] [0032] [0035] [0036] [0064]); having the pharmacist fill said prescription utilizing said unfilled prescription data and present a filled prescription to said particular patient (Denny; paragraphs [0035] [0036] [0049] [0063] [0064]), wherein said filled prescription contains a presented pharmaceutical type in a presented quantity (Denny; paragraphs [0031] [0032] [0036] [0049] [0063] [0064]); entering filled prescription data into said database (Denny; paragraphs [0035] [0041]), comparing said filled prescription data with said unfilled prescription data (Denny; paragraph [0053]); and generating a warning if said filled prescription data does not match said unfilled prescription data, wherein said warning is forwarded to said physician who initial wrote said prescription (Denny; paragraph [0053]).

While Denny provides for the pharmacist inputting information representative or indicative of a prescription to be filled (Denny; paragraph [0035]) and subsequently provides for the pharmacist inputting a code indicating that a prescription has been filled into the host system (Denny; paragraph [0041]), Denny fails to specifically indicate that the pharmacist enters filled prescription data that includes pharmaceutical type, quantity, cost or other information.

However, as is evidenced by Borsand et al., it is well known in the prescription fulfillment art for the pharmacist to record or enter into a database, information regarding the specifics of a filled prescription including cost, drug type, and quantity administered to the patient. Accordingly, Borsand et al. teach a method wherein said filled prescription data includes information for said

presented pharmaceutical type and said presented quantity (Borsand et al.; paragraphs [0005] [0040] [0056] [0064] [0086] [0118]).

Applicant has further amended claim 1 with regard to the "entering filled prescription data..." step to further specify "..entering filled prescription data into said database should said presented pharmaceutical type or said presented quantity vary in any manner from said recommended pharmaceutical type or said recommended quantity stated in said prescription wherein said filled prescription information includes information for said presented pharmaceutical type and said presented quantity actually present in said filled prescription;"

As per these elements, Borsand et al. disclose the electronic representation of a filled prescription is generated in a substantially simultaneous manner with the filling of the prescription and the distribution of the prescribed pharmaceutical (Borsand et al.; paragraph [0084]). Borsand et al. additionally disclose that during prescription fulfillment at the pharmacy, the prescription is re-evaluated in terms of reimbursement rules and medical appropriateness and that if for any appropriate business or medical reason the filling of a prescription should not occur, the pharmacist can cancel or potentially even modify the prescription as appropriate (Borsand et al.; paragraph [0087]). Borsand et al. further disclose that the pharmaceutical type and quantity are entered into the system as a matter of protocol during the generation of the prescription by a physician (Borsand et al.; paragraph [0064]). While Borsand et al. fail to redundantly consider the entry of quantity and type by the pharmacist during an "appropriate" modification of the prescription, Examiner submits that it is reasonable to assume these steps are repeated by the

pharmacist making changes to the prescription. Examiner further submits that the noted assumption is justified in view of the objectives of the Borsand et al., which include the desire to "prevent a pharmacist from filling a prescription at half the strength but twice the volume and cost" (Borsand et al.; paragraphs [0005] [0082]). In view of the above noted teachings, Examiner submits that the collective teachings of Borsand et al. inherently include the entry of the pharmaceutical type and quantity actually dispensed by the pharmacist.

Applicant has further amended claim 1 with regard to the "comparing" step to specify"...analyzing said filled prescription data to determine if differences between said filled prescription data and said unfilled prescription data are justifiable;"

As per this element, by the rationale applied above, Examiner submits that the same data entry and review process occurs with regard to pharmacist proposed changes or modifications to a prescription as occur with regard to initial prescriptions. Accordingly, Borsand et al. disclose analyzing the filled prescription data to determine if changes are justified.

Applicant has further amended claim 1 with regard to the "warning" step to include ..."generating a warning if differences between said filled prescription data and said unfilled prescription data are unjustifiable,..."

As per this element, Examiner maintains that the "signal" transmitted to the healthcare provider system in the event that prescription information entered into the database at the pharmacy

system does not match the prescription information stored in the database (previously entered by the provider) constitutes "generating a warning if differences between said filled prescription data and said unfilled prescription data are unjustifiable" under the broadest reasonable interpretation of the amended claim language.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have combined the teachings of Denny with those of Borsand et al. Such combination would have resulted in a system and method that enabled the entry of prescription information including prescribed drug and dosage level prescribed to a patient, by a physician, into a host system (Denny; Abstract). Such a method/system would have further provided for the retrieval of the prescribed drug and dosage level information from the host system, by a pharmacist, for the purpose of filling the prescription for the patient (Denny; Abstract). Additionally, such a system/method would have enabled the pharmacist to enter information indicating that the prescription had been filled into the host system for the review of the prescribing physician (Denny; paragraphs [0035] [0041] [0053]). Lastly, such a method would have been enabled by a integrated system in which the payor, PBM, pharmacy, and provider access and manipulate the same information, including prescribed drug, quantity/dosage, refills, cost, and reimbursement rules (Borsand et al.; paragraphs [0040] [0064]). The motivation to combine the teachings would have been to enable a provider to monitor the filling of a prescription such that the prescription can be cancelled in the event of fraud, abuse, or mistakes, such as a pharmacist filling a prescription at half strength but twice the volume and cost (Borsand et al.; paragraphs [0005] [0120]).

As per (currently amended) claim 2, Denny teaches a method wherein said step of entering unfilled prescription data includes the substeps of: having a physician access said database (Denny; paragraphs [0010] [0031]); authenticating the identity of said physician (Denny; paragraph [0043]); and having said physician enter said unfilled prescription data into said database (Denny; Abstract and paragraph [0031]).

As per (currently amended) claim 3, Denny teaches a method wherein said step of retrieving said unfilled prescription data from said database includes the substeps of: having said medical professional access said database (Denny; paragraphs [0035] [0036]); authenticating the identify of said pharmacist (Denny; paragraph [0043]); and providing said pharmacist with said unfilled prescription data through said database (Denny; paragraphs [0035] [0036]).

As per claim 4, Denny teaches a method further including the step of registering physicians authorized to access said database (Denny; paragraphs [0027] [0029] [0043] [0047]).

As per (currently amended) claim 5, Denny teaches a method further including the step of registering pharmacists authorized to access said database (Denny; paragraphs [0027] [0029] [0043] [0047]).

As per claim 6, Denny teaches a method wherein said step of entering filled prescription data further includes entering information regarding pharmaceutical brand, and pharmaceutical cost (Borsand et al.; paragraphs [0040] [0056] [0066] [0070] and Fig. 1).

Claim 7 has been cancelled.

As per (currently amended) claim 8, Borsand et al. teach a method wherein said step of generating a warning includes providing a warning to an insurance company that said pharmacist failed to properly fill said prescription (Borsand et al.; paragraphs [0005] [0034] [0120]-[0122] and Fig. 11).

NOTE: Borsand et al. provide a system and method that supports tracking pharmaceutical, prescription, and related information throughout the life cycle of the pharmaceutical or prescription (Borsand et al.; paragraph [0034]). Borsand et al. further specify that information tracking can be in a proactive and real-time manner (Borsand et al.; paragraph [0034]). Borsand et al. further teach that a purpose of proactive and real-time tracking of information is to identify instances of fraud or error, such as a pharmacist filling a prescription at half strength and half strength and twice the volume and cost (Borsand et al.; paragraph [0005]). Examiner's interpretation of the above noted teachings of Borsand et al. constitute a "warning" mechanism indicating that a pharmacist has failed to fill a prescription properly.

As per (currently amended) claim 9, Denny teaches a method wherein said database is maintained at a central facility and said database is accessed by said physician and said pharmacist by a telecommunications link (Denny; Abstract paragraphs [0023] [0039] [0041]).

Regarding claims 2-6 and 8-9, the obviousness and motivation to combine as discussed with regard to claim 1 above are applicable to claims 2-6 and 8-9 and are herein incorporated by reference.

As per (currently amended) claim 12, Denny teaches a method of verifying changes made by a pharmacist to medical prescriptions to reduce fraud and mistake in the filling of medical prescriptions, said method comprising the steps of: entering unfilled prescription data into a secure database, wherein said unfilled prescription data corresponds to a patient's unfilled prescription for at least one pharmaceutical (Denny; paragraphs [0010] [0027] [0030] [0031]); retrieving said unfilled prescription data from said database at a pharmacy (Denny; paragraphs [0011][0012][0032][0035][0036][0064]); having a pharmacist at said pharmacy provide volume of said at least one pharmaceutical as directed by said unfilled prescription data (Denny; paragraphs [0035] [0036] [0049] [0063] [0064]); entering filled prescription data into said database (Denny; paragraphs [0035] [0041]); comparing said filled prescription data to said to said unfilled prescription data (Denny; paragraph [0053]); and generating a warning if said unfilled prescription data and said unfilled prescription data differ (Denny; paragraph [0053]).

While Denny provides for the pharmacist inputting information representative or indicative of a prescription to be filled (Denny; paragraph [0035]) and subsequently provides for the pharmacist inputting a code indicating that a prescription has been filled into the host system (Denny; paragraph [0041]), Denny fails to specifically indicate that the pharmacist enters filled prescription data that includes pharmaceutical type, quantity, cost or other information.

However, as is evidenced by Borsand et al., it is well known in the prescription fulfillment fields for the pharmacist to record or enter into a database, information regarding the specifics of a filled prescription including cost, drug type, and quantity (i.e., volume) administered to the patient. Accordingly, Borsand teaches a method wherein said filled prescription data identifies, said at least one pharmaceutical and said volume provided by said pharmacist (Borsand et al.; paragraphs [0040] [0056] [0066] [0070] and Fig. 1).

Applicant has further amended claim 12 with regard to the pharmacist provision of "volume...as directed" step to specify "...having a pharmacist at said pharmacy fill said unfilled prescription, wherein said pharmacist exercises discretion to alter said prescription so that the filled prescription varies from said unfilled prescription data;"

Applicant has additionally amended claim 12 with regard to the "entering filled prescription data..." step to further specify that the entered "volume" data is "...volume actually provided by said pharmacist as said filled prescription;"

Applicant has further amended claim 12 with regard to the "comparing..." step to specify that "comparing said filled prescription data to said unfilled prescription data to identify discretion exercised by said pharmacist;"

As per these elements, Borsand et al. disclose the electronic representation of a filled prescription is generated in a substantially simultaneous manner with the filling of the prescription and the distribution of the prescribed pharmaceutical (Borsand et al.; paragraph [0084]). Borsand et al. additionally disclose that during prescription fulfillment at the pharmacy, the prescription is re-evaluated in terms of reimbursement rules and medical appropriateness and that if for any appropriate business or medical reason the filling of a prescription should not occur, the pharmacist can cancel or potentially even modify the prescription as appropriate (Borsand et al.; paragraph [0087]). Borsand et al. further disclose that the pharmaceutical type and quantity are entered into the system as a matter of protocol during the generation of the prescription by a physician (Borsand et al.; paragraph [0064]). While Borsand et al. fail to redundantly consider the entry of quantity and type by the pharmacist during a modification of the prescription, Examiner submits that it is reasonable to assume these steps are repeated upon the pharmacist making changes to the prescription. Examiner further submits that the noted assumption is justified in view of the objectives of the Borsand et al., which include the desire to "prevent a pharmacist from filling a prescription at half the strength but twice the volume and cost" (Borsand et al.; paragraphs [0005] [0082]). Examiner submits that the data entry, prescription modification, and prescription review on the basis of compliance with reimbursement rules and

medical appropriateness encompass Applicant's above amended steps directed to the entry of filled data and a determination of justified or unjustified discretion exercised by the pharmacist.

Applicant has further amended claim 12 with regard to the "generating a warning" step to include "generating a warning if said discretion exercised by said pharmacist is unjustified".

As per this element, Borsand et al. disclose the modification of a prescription, as appropriate, by a pharmacist at the time of filling (Borsand et al.; paragraph [0087]). Examiner reiterates and maintains for the reasons set forth above that modifications made by a pharmacist would be subject to the same re-evaluation of the prescription in terms of reimbursement rules and medical appropriateness. Examiner submits that this re-evaluation constitutes a determination as to whether the discretion exercised by the pharmacist is unjustified. Further, the pharmacist would be informed of an inappropriate modification, as is the case upon filling a prescription as written. Examiner submits that the determination of "If for any appropriate business or medical reason the filling of a prescription should not occur." constitutes a warning that the discretion is unjustified (Borsand et al.; paragraph [0087]).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have combined the teachings of Denny with those of Borsand et al. Such combination would have resulted in a system and method that enabled the entry of prescription information including prescribed drug and dosage level prescribed to a patient, by a physician, into a host system (Denny; Abstract). Such a method/system would have further provided for the retrieval of the

prescribed drug and dosage level information from the host system, by a pharmacist, for the purpose of filling the prescription for the patient (Denny; Abstract). Additionally, such a system/method would have enabled the pharmacist to enter information indicating that the prescription had been filled into the host system for the review of the prescribing physician (Denny; paragraphs [0035] [0041] [0053]). Lastly, such a method would have been enabled by a integrated system in which the payor, PBM, pharmacy, and provider access and manipulate the same information, including prescribed drug, quantity/dosage, refills, cost, and reimbursement rules (Borsand et al.; paragraphs [0040] [0064]). The motivation to combine the teachings would have been to enable a provider to monitor the filling of a prescription such that the prescription can be cancelled in the event of fraud, abuse, or mistakes, such as a pharmacist filling a prescription at half strength but twice the volume and cost (Borsand et al.; paragraphs [0005] [0120]).

As per (previously presented) claim 13, Denny teaches a method wherein said step of entering unfilled prescription data includes the substeps of : having a physician access said database (Denny; paragraphs [0010][0031]); authenticating the identity of said physician (Denny; paragraph [0043]); and having said physician enter said unfilled prescription data into said database (Denny; Abstract and paragraph [0031]).

As per (previously presented) claim 14, Denny teaches a method wherein said step of retrieving said unfilled prescription data from said database includes the substeps of: having said pharmacist access said database (Denny; paragraphs [0035][0036]); authenticating the identity of

said pharmacist (Denny; paragraph [0043]); and providing said pharmacist with said unfilled prescription data through said database (Denny; paragraphs [0035][0036]).

As per claim 15, Denny teaches a method further including the step of registering physicians authorized to access said database (Denny; paragraphs [0027] [0029] [0043] [0047]).

As per claim 16, Denny teaches a method further including the step of registering pharmacists authorized to access said database (Denny; paragraphs [0027] [0029] [0043] [0047]).

As per (currently amended) claim 17, Borsand et al. teach a method wherein the step of generating a warning includes providing a warning to said physician (Borsand et al.; paragraphs [0005] [0056] [0086] [0118] [0120]-[0122] *see analysis claim 8).

As per (previously presented) claim 18, Borsand et al. teach a method wherein said step of generating a warning includes providing a warning to an insurance company (Borsand et al.; paragraphs [0005] [0034] [0120]-[0122] and Fig. 11 *see analysis claim 8).

Regarding claims 13-18, the obviousness and motivation to combine as discussed with regard to claim 12 above are applicable to claims 13-18 and are herein incorporated by reference.

[4] Claims 10-11 and 19-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Denny and Borsand et al. as applied to claims 1 and 12 above, and further in view of Keresman, III et al. (United States Patent Application Publication #2001/0047281).

Regarding claims 10-11 and 19-20, while Denny teaches authenticating and identifying provider and pharmacist systems accessing the host system (Denny; paragraph [0043]), Denny fails to specifically teach biometric identification as part of the security protocol.

However, as evidenced by Keresman, III et al., the use of biometric identification of registered doctors, pharmacies, and other participants is well known in the prescription drug fulfillment art (Keresman III et al.; paragraphs [0008] [0009] [0015] [0050] [0056]).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have combined the teachings of Denny and Borsand et al., as applied to claim 1 and 12 above, with those of Keresman, III et al. with the intention of determining that the requesting system is a valid system by using password protection or other security methods known in the art (Denny; paragraph [0043]). The motivation to combine the teachings would have been to employ a well-known security protocol to provide a suitable degree of security, which prevents unauthorized access to a patient's confidential medical and pharmaceutical records (Keresman, III et al.; paragraph [0004]).

Response to Remarks/Amendment

Applicant's remarks filed 16 July 2007 have been fully considered but they are not persuasive. Applicant's remarks have been fully addressed in the rejections of claims 1 and 12 set forth in the preceding sections of the present Office Action.

In response, all of the limitations which Applicant disputes as missing in the applied references, including the features newly added in the 16 July 2007 amendment, have been fully addressed by the Examiner as either being fully disclosed or obvious in view of the collective teachings of Denny, Borsand et al., and Keresman III, based on the logic and sound scientific reasoning of one ordinarily skilled in the art at the time of the invention, as detailed in the remarks and explanations given in the preceding sections of the present Office Action and in the prior Office Action (8 March 2007), and incorporated herein.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert D. Rines whose telephone number is 571-272-5585. The examiner can normally be reached on 8:30am - 5:00pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on 571-272-6776. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

RDR

10/15/07

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